

# SACGT to SACGHS



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SACGHS Executive Secretary

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Presentation to CLIAC

# Secretary's Advisory Committee on Genetic Testing (SACGT)

- Mandate: to advise the Secretary of HHS on all aspects of the use and development of genetic tests
- Scope: recommending policies for the safe and effective incorporation of genetic tests into health care; assessing the effectiveness of oversight measures; and identifying research needs
- Chartered: June 1998 and June 2000
- Operated: June 1999 - August 2002

# SACGT Areas of Interest

- Oversight of genetic tests
- Classification of genetic tests
- Genetic discrimination in health insurance and employment
- Impact of gene patents and licensing
- Third parties in genetic research

# SACGT Areas of Interest

- Genetics education of health professionals
- Reimbursement for genetic tests and services
- Informed consent for genetic tests
- Public understanding of genetic testing
- Genetic tests for rare diseases
- HHS efforts to advance the translation of genetic tests

# Key Oversight Recommendations

- All new genetic tests should be regulated by FDA, using an innovative, flexible approach
- CLIA should be augmented to enhance the quality of genetic testing laboratories
- All investigational genetic tests should undergo IRB review
- Enhanced data collection and dissemination efforts, through public-private collaborations, are needed to ensure continued analysis of tests in post-market period

# Departmental Review of Advisory Committees

- In summer 2002, HHS undertook a review of all advisory committees to assess need
- Conclusion: Advice is needed on many genetics issues, not only on genetic testing
- SACGT's charter was revised to form a new committee with a broader scope covering genetic technologies and their social as well as health-related implications

# Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS)

- Mandate: to explore, analyze, and deliberate on the broad range of human health and societal issues raised by the development and use, as well as potential misuse, of genetic technologies and make recommendations to the Secretary of HHS, and other entities as appropriate

# SACGHS Scope

- Assessing the integration of genetic technologies into health care and public health
- Studying the clinical, ethical, legal and societal implications of new medical applications and emerging technological approaches to clinical testing
- Identifying opportunities and gaps in research and data collection efforts
- Exploring the use of genetics in bioterrorism



# SACGHS Scope

- Examining the impact of patent policy and licensing practices on access to genetic technologies
- Analyzing uses of genetic information in education, employment, insurance, including health, disability, long-term care, and life, and law, including family, immigration, and forensics
- Serving as a public forum for the discussion of emerging scientific, ethical, legal and social issues raised by genetic technologies

# SACGHS Composition

- Molecular biology
- Human genetics
- Health care
- Public health
- Ethics
- Law
- Psychology
- Social sciences
- Consumer advocacy
- Insurance
- Education
- Occupational health
- Bioterrorism
- Forensics

# SACGHS Membership

## Chair

Edward R.B. McCabe, MD, PhD  
UCLA

## Members

Cynthia Berry, JD  
Wexler & Walker Public Policy Associates

Barbara Willis Harrison, MS  
Howard University

Christopher Hook, MD  
Mayo Medical School

Eric Lander, PhD  
MIT Whitehead Institute for Genome Research

Debra Leonard, MD, PhD  
University of Pennsylvania

Brad Margus  
A-T Children's Project, Perlegen Sciences

Agnes Masny, RN, MPH, MSN  
Temple University

Joan Reede, MD, MPH, MS  
Harvard Medical School

Reed Tuckson, MD  
UnitedHealth Group

Huntington Willard, PhD  
Duke University

Emily Winn-Deen, PhD  
Roche Molecular Systems

Kimberly Zellmer, JD

# SACGHS *Ex Officios*

## HHS Agencies - 9

- ACF
- AHRQ
- CDC
- CMS
- FDA
- HRSA
- NIH
- OCR
- OHRP

## Other Departments - 7

- Commerce
- Defense
- Education
- Energy
- Justice
- Labor
- EEOC

# Priority Setting Process

- The 16 *Ex Officio* agencies were surveyed about priority issues and specific questions SACGHS should address
- Individual agency priorities and an aggregated set of priorities were shared with SACGHS to assist in its priority setting process

# CDC's Priority Issues

1. Population research on the genetic basis of disease
2. Federal/State role in integration
3. Assessing the health effects of genetically-altered biological agents
4. Collection of genetic samples for public health threats
5. Assessing public benefit of genetic tests

# CDC's Priority Issues (cont)

6. Expansion of DNA collection to improve health services
7. Adequacy of State protections against genetic discrimination
8. Fears among minority groups of misuse of genetic information
9. Impact gene patents and licensing on the accessibility, availability, and affordability of genetic technologies

# CMS's Priority Issues

- Need for clinical standards to determine clinical readiness
- Assessments for insurance coverage
- Preparedness of the healthcare system for incorporation of genetic technologies
- Effect of incorporation on healthcare financing system
- Health insurance coverage of tests lacking clinical utility
- Gaps in research and data
- Effectiveness data



# FDA's Priority Issues

- Lessons learned from CF carrier screening
- DTC advertising issues
- National/international coordination in the development of regulatory programs, standards and guidelines

# Aggregated Priorities

1. Use/misuse of genetic information in insurance, employment, education and law (8)
2. ELSI implications associated with using genetic technologies to screen or select for “desirable” or “undesirable” traits (6)
3. Standards for assessing when genetic technologies are ready to be used in clinical practice (5)
4. ELSI implications associated with new health related applications of genetic technologies (5)
5. Guidance for gene banking for research and forensic use (5)

# Aggregated Priorities

6. Use of genetic technologies for bioterrorism (5)
7. Impact of patenting and licensing practices on the availability, accessibility, and affordability of genetic technologies (5)
8. Genetic literacy of the public about the scientific, ethical, legal, social issues raised by genetic technologies (5)
9. Need for additional measures to strengthen current oversight of genetic tests (4)
10. Impact of the Privacy Rule on genetic data collection (4)

# SACGHS Inaugural Meeting

- Current status of genetic technologies and their current uses
- Emerging developments and research directions
- Health care financing of genetic technologies
- Current issues related to patents and licensing practices
- Current understanding of the ethical, legal, social implications of genetic technologies
- Identify and prioritize issues to be addressed and develop a work plan

# Short Range Action Items

- Draft letter to HHS Secretary supporting legal protections against genetic discrimination in health insurance and employment in S.1053
- Collect information from Federal agencies and the private sector on activities addressing education and training of professionals in genetics and analysis of genetics workforce issues
- Organize briefing by regulatory agencies on their roles in oversight of genetic tests, laboratories, and marketing and efforts to strengthen oversight

# Upcoming SACGHS Meeting

- Session on the oversight of genetic tests and laboratories and the role of pharmacogenetics
  - Oversight of genetic tests through CLIA by CMS (Judy Yost) and CDC (Joe Boone)
  - Impact of pharmacogenomics on prescription drug labels (Larry Lesko)
  - Oversight of genetic tests by FDA (David Feigal and Steve Gutman)
  - Presentation on FTC's role in regulating marketing of genetic technologies (Matthew Daynard)

# Upcoming SACGHS Meeting

- Session on genetics education, training, and workforce issues
  - Federal activities (Sam Shekar)
  - Genetics workforce study (Judith Cooksey)
  - Efforts by professional societies and organizations (Joann Boughman and Joseph McInerney)
  - Genetic counselor training program needs (Robin Bennett)
- Session on UK and Australia's efforts to address issues involving genetic technologies
- Update on genetic discrimination legislation

# Longer Range Issues

- Diffusion of innovation and its implications for access to technologies
- Initiatives related to health disparities and the role of genetics
- Large population studies and resources needed to advance understanding of genotype-phenotype correlations and the genetic basis of common diseases
- Effects of patents and licensing practices on access to clinical genetic technologies



# SACGHS Contact Information

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